REMARKS

Upon entry of the above amendment, claims 1-13, 15 and 18-20 will be pending in the present application. Applicants respectfully submit that the amendments to the claims do not add any new matter within the meaning of 35 USC §132.

1. Rejection of claims 18 and 20 under 35 U.S.C. §112, 1st paragraph

The Official Action states that claims 18 and 20 are rejected under 35 U.S.C. §112, 1st paragraph "as failing to comply with the enablement requirement." In this regard, the Official Action states, in relevant part:

> In regard to the enablement rejection of claims 18 and 20, the applicants have provided several references to support the enablement. Although the compounds in all these references are shown to inhibit PDE4 yet they are structurally very different from the instant compounds. The applicants have not provided any references for structurally closely related compounds to have well known utility for treating diseases such as allergic rhinitis, rheumatoid arthritis, dermatoses, ulcerative colitis and crohn's disease. On the other hand, several PDE4 inhibitors with diverse structures are currently in phase I, II and III clinical trials for treatment of asthma and/or COPD. Based on this information, the instant compounds will have utility for treating asthma and COPD but not all other diseases.

RESPONSE

Applicants respectfully traverse this rejection.

Applicants respectfully submit that the presently claimed diseases are enabled by the instant specification, especially in view of the references submitted in the Information Disclosure Statement filed with the previously filed Response and Amendment. In particular, applicants previously amended claims 18 and 19 do recite specific diseases. Applicants have amended claim 18 to recite "asthma, COPD, allergic rhinitis, rheumatoid arthritis, dermatoses, ulcerative colitis or Crohn's disease". Claim 19 recites the diseases "asthma and/or COPD". Each reference of the IDS was discussed in detail in the previous Response and Amendment with reference to its demonstration of enablement of the particular disease. Despite such evidence presented by applicants, the Examiner has stated that only asthma and COPD are enabled. Applicants respectfully disagree.

First, applicants respectfully point out that the Examiner of this application has presented conflicting rejections regarding the enablement of these diseases. In particular, prior to issuance of the present Official Action, the Examiner telephoned applicants' representative and discussed that all pending claims were allowed except for claim 20 and claim 18, which he indicated as only enabled for asthma, COPD, allergic rhinitis and Crohn's disease. During this telephone conference, the Examiner agreed to allow all claims if he was authorized to prepare an Examiner's Amendment to claim 18, canceling all diseases except for asthma, COPD, allergic rhinitis and Crohn's disease, as well as canceling claim 20.

However, applicants' representative did not authorize such an amendment. In the present Official Action, the Examiner now states that only asthma and COPD are enabled by the instant specification, but allergic rhinitis and Crohn's disease, previously indicated as enabled and allowable, are now not enabled, even in view of the evidence demonstrating their enablement provided in the IDS references filed April 7, 2006. Applicants respectfully request clarification how two diseases can be indicated as enabled and allowable one day, and then indicated as not enabled and not allowable the next.

The law on enablement, as set forth in In re Marzocchi, 439 F.2d 220, 223-234 (CCPA 1971), requires the Patent Office to provide specific reasons for a §112 rejection. However, the Examiner has failed to properly provide such reasons. Further, the Examiner has provided no evidence to contradict the assertion in the specification that the claimed compounds would be useful for treating the specified diseases listed in claims 18-20. Instead, the Examiner has merely stated that the diseases are not so enabled for the specified diseases, which is contrary to In re Chilowsky, 229 F.2d 457, 462 (CCPA 1956).

Despite the Examiner's mere statements to the contrary, applicants have gone beyond the clear basis in the specification that the presently claimed diseases are enabled by submitting several references from public knowledge supporting enablement and utility. Thus, the state of the art suggests a correlating

relationship between PDE4 inhibition and the presently claimed diseases.

Even if the Examiner did have evidence that PDE4 inhibition might not correlate to the presently claimed diseases, which the Examiner does not, the Examiner would still be required to weigh the evidence for and against correlation and decide whether one skilled in the art would accept PDE4 inhibition as reasonably correlating to the given diseases (analogously to In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995)).

Since the initial burden is on the Examiner to give legitimate reasons for the lack of enablement, when possible to be supported by real evidence, the Examiner must also give reasons for a lack of correlation. A rigorous or an inevitable exact correlation is not required as stated in Cross v. Ilzuka, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985). However, the Examiner has admitted on the record that "the compounds in all these [IDS] references are shown to inhibit PDE4". Accordingly, applicants have established a correlating link between PDE4 inhibition and treatment of the presently claimed diseases.

As such, the specification sufficiently teaches the invention in a manner which would enable a person of ordinary skill in the art to practice the invention without undue experimentation.

Accordingly, presently pending claims 18 and 20 are fully enabled by the instant specification in view of the evidence previously provided.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 18 and 20.

2. **Rejection of claims 1-13, 15 and 18-20 under 35 U.S.C. §112, 1st paragraph**

The Official Action states that claims 1-13, 15 and 18-20 stand rejected under 35 U.S.C. §112, 1st paragraph as failing to comply with the enablement requirement. In particular, the Official Action states, in relevant part:

> The instant claims are directed to solvates, hydrates hydrate of a salt or salt of solvate of instant compounds of formula (I), pharmaceutical compositions containing them and methods of using them. However, the specification is not enabling for preparing solvates, hydrates, hydrate of a salt or salt of solvate of instant compounds of formula (I).

RESPONSE

Applicants respectfully traverse the rejection of claims 1-13, 15 and 18-20.

However, solely to remove the basis of this rejection, applicants have amended claims 1-13, 15 and 18-20 to remove "hydrate", "solvate", "hydrate of a salt" and "solvate of a salt".

Accordingly, applicants respectfully request that the rejection of claims 1-13, 15 and 18-20 be reconsidered and withdrawn.

CONCLUSION

Based upon the evidence and amendments submitted herewith and the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections and allow pending claims 1-13, 15 and 18-20. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,
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